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## REMARKS/ARGUMENTS

### Claim rejections under 35 USC § 112, second paragraph

*The Examiner rejects Claims 4, 28, and 54 because the recitation of "high concentration" is indefinite.*

Applicants point out that on page 7, lines 17-19, it states that, "a 'high concentration' is a concentration that generally exceeds the molar concentration of sucrose in a medium comprising 3% (w/v) sucrose." Applicants have amended Claims 4, 28, and 54 by deleting the words "high concentration" and including the words "wherein the medium comprises an osmotic potential greater than that produced by a medium containing 3% (w/v) sucrose."

*The Examiner rejects Claim 54 because the recitation of "further comprising" is indefinite.*

Applicants have amended the claim so that it is no longer indefinite.

*The Examiner rejects Claim 55 because the use of "said nucleotide construct" lacks antecedence.*

Applicants have amended the claim so that it is now in proper form.

*The Examiner rejects Claim 55 because the "rupture disk rating of about 200" lacks a unit of measure.*

Applicants have amended the claim by adding the unit "p.s.i".

### Claim rejections under 35 USC § 102

*The Examiner rejects Claims 1-2, 4-6, 11-12, 25-26, 28-30, 35-36, 49-50, 52-54 and 58-60 under 35 U.S.C. 102(b), as being anticipated by Dunder E. et al. in Maize Transformation by Microprojectile Bombardment of Immature Embryos; Springer-Verlag, Berlin-Heidelberg; pages 127-138. The Examiner states that Dunder teaches excision and direct placement of immature maize embryos upon osmotic treatment medium for 3 to 4 hours for a same day transformation by*

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*microprojectile bombardment (page 134), wherein the osmotic pretreatment comprises auxin-depleted MS medium ...."*

The Applicants disagree with the Examiner. To serve as an anticipating reference, the reference must enable that which it is asserted to anticipate. "A claimed invention cannot be anticipated by a prior art reference if the allegedly anticipatory disclosures cited as prior art are not enabled." *Amgen, Inc. v. Hoechst Marion Roussel, Inc.*, 314 F.3d 1313, 1354, 65 USPQ2d 1385, 1416 (Fed. Cir. 2003). The principles underlying application of the criteria of enablement to the content of the prior art were discussed in *In re Donohue*, 766 F.2d 531, 226 USPQ 619 (Fed. Cir. 1985):

"It is well settled that prior art under 35 U.S.C. § 102(b) must sufficiently describe the claimed invention to have placed the public in possession of it. Such possession is effected if one of ordinary skill in the art could have combined the publication's description of the invention with his own knowledge to make the claimed invention. Accordingly, even if the claimed invention is disclosed in a printed publication, that disclosure will not suffice as prior art if it is not enabling."

In *Elan Pharmaceuticals Inc. v. Mayo Foundation for Medical Education and Research* 1376, 68 USPQ2d (Fed. Cir. 2003) it states, "The disclosure in an assertedly anticipating reference must be adequate to enable possession of the desired subject matter. It is insufficient to name or describe the desired subject matter, if it cannot be produced without undue experimentation."

Applicants have amended Claim 1 for clarification purposes. Claim 1 now reads as follows. A method for producing a maize cell in which a nucleotide of interest is stably integrated, said method comprising: a) obtaining at least one immature embryo from a maize ear; and b) introducing said nucleotide construct into at least one cell of said immature embryo by microprojectile bombardment within 24 hours of obtaining said immature embryo. Dunder E. *et al.* (1995) does not

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anticipate the stable transformation of freshly isolated maize embryos. The article reads, "If the immature embryos are to be bombed on the day of plating, they can be plated and arranged directly onto the osmotic treatment target plates as described below." The article goes on to read, "We have delivered genes after 1 to 4 days of culture with varying degrees of success." However, Dunder E. et al. does not teach fresh embryo transformation because the publication does not enable the stable transformation of freshly isolated embryos. Applicants also submit that other references teach away from the invention. For example, Songstad *et al.* (published in 1996 and submitted as A5 in the IDS), findings indicate that they were unable to transform freshly isolated embryos. See first paragraph under "Results and Discussion" on page 179 and also Table 2 on page 180 of the publication. The results of Brettschneider *et al.* (published in 1997 and submitted as A3 in the IDS) also teach away from obtaining stably transformed plants by bombarding freshly isolated immature embryos. On page 739, the authors report that, "A strong inhibition of somatic embryogenesis was observed when immature embryos were bombarded directly after isolation." The authors also report in Table 4, on page 742, that when pre-culture time was less than a day no stable transformation events were recovered.

#### **Claim rejections under 35 USC § 103**

*The Examiner rejects Claims 1-2, 4-6, 11-12, 25-26, 28-30, 35-37, 49-50, 52-57 and 58-61 under 35 U.S.C. 103(a), as being unpatentable over Dunder E. et al. in Maize Transformation by Microprojectile Bombardment of Immature Embryos; Springer-Verlag, Berlin-Heidelberg; pages 127-138. The Examiner states that Dunder teaches the optimization of design parameters for particle bombardment.*

Applicants disagree with the Examiner. The method of producing a stably transformed maize cell using a freshly isolated embryo is not obvious over Dunder E. et al. (1995). On page 129 Dunder *et al.* reads, "Many factors influence the degree of success in delivering genes to living cells and tissues using microprojectile

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bombardment. Each factor discussed below has been shown to affect the efficiency of gene delivery to maize immature embryos." Dunder *et al.* goes on to describe genes, osmotic treatments, mechanical settings, target protection, target saturation, target orientation, and particle preparation as being the factors that affect efficiency. In the section of the publication under the heading "Detailed Procedure" on page 134, last sentence of step number 3, it reads, "We have delivered genes after 1 to 4 days of culture with varying degrees of success." Also as stated previously, other research teaches away from the invention. Songstad *et al.* and Brettschneider *et al.* *supra* indicate that no stable transformation events were recovered from immature embryos that were bombarded less than 1 day after being isolated. Songstad *et al.* also teaches away from the Applicants invention when it discusses why freshly isolated embryos are not amenable to transformation whereas 2 and 4 day pre-cultured embryos are amenable to transformation. Songstad *et al.* states on page 181, in the second full paragraph, "Based on the histological evidence, it is likely that precultured immature embryos are amenable to transformation due to dividing epidermal cells of the scutellum that give rise to embryogenic calli."

If all the elements of an invention are in prior art references,

"a proper analysis under § 103 requires, *inter alia*, consideration of two factors: (1) whether the prior art would have suggested to those of ordinary skill in the art that they should make the claimed composition or device, or carry out the claimed process; and (2) whether the prior art would also have revealed that in so making or carrying out, those of ordinary skill would have a reasonable expectation of success."

*In re Vaeck*, 947 F.2d 488, 493 [20 USPQ2d 1438] (Fed. Cir. 1991) (citing *In re Dow Chem. Co.*, 837 F.2d 469, 473 [5 USPQ2d 1529] (Fed. Cir. 1988)). Both the suggestion and the reasonable expectation of success "must be founded in the prior art, not in the applicant's disclosure." *Id.* A reasonable expectation of success is not found in Dunder *et al.*

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In view of the above comments and amendments, withdrawal of the outstanding rejections and allowance of the claims is respectfully requested.

Respectfully submitted.



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